REMARKS

Applicants have carefully reviewed the Office Action mailed May 23, 2007, and thank Examiner Rogers for his review of the pending claims. By way of Applicants' August 10, 2005 amendment, claims 1-33 were pending and new claim 33 was added. By way of Applicants' February 21, 2006 amendment, claims 1, 17, 23 and 27 were amended, claims 2-4 and 18-20 were canceled without prejudice and new claims 34-37 were added. By way of Applicants' March 20, 2007 amendment, claims 1, 17, 23, 27 and 36 were amended, claim 34 was cancelled without prejudice and new claims 38-44 were added. Accordingly, claims 1, 5-17, 21-33 and 35-44 were pending in this application. In this response, claims 1, 17, 23, 25, 26, 27, and 37 are amended, and claims 5, 8, 9, 22, 33, and 36 are canceled without prejudice. No new claims or new subject matter are added.

At least for the reasons set forth below, Applicants respectfully traverse the rejections. Further, Applicants believe that there are also reasons other than those set forth below why the pending claims are patentable and reserve the right to set forth those reasons, and to argue for the patentability of claims not explicitly addressed herein, in future papers. Applicants respectfully request reconsideration of the present application in view of the above amendments and the following remarks.

Election/Restrictions

The Examiner has required restriction between:

Group I, claims 1, 5 – 17, 21-33, and 35-37drawn to a method for forming an endovascular occlusion comprising the step of controlling injection of purified alginate liquid and injection of a calcium chloride solution to a targeted area within a vascular system, classified as class 424, subclass 423; and

Group II, claims 38 – 44 drawn to a method for forming an endovascular occlusion comprising providing a catheter comprised of a microcatheter having a first lumen with a second catheter disposed inside the first lumen, the second catheter having a second lumen which is concentric with the first lumen, the distal end of the second lumen being adjustable with respect to the distal end of the first lumen and controlling injection of purified alginate liquid and injection of

a calcium chloride solution to a targeted area through the catheter, classified as class 604, subclass 508. The Examiner concluded that there had been a constructive election of Group I claims by original presentation for prosecution on the merits.

The Examiner's reasons for the restriction were, *inter alia*, that the inventions are distinct as combinations and subcombinations of certain types with certain characteristics, and/or are independent or distinct, all as more specifically described in the reasons stated in the Election/Restriction Requirement, in which Applicants do not acquiesce. The Applicants respectfully submit their belief that, the reasons set forth by the Examiner notwithstanding, similar or overlapping searches may be required for each claim group identified by the Examiner. Accordingly, it is respectfully submitted that the Examiner will be required to search art related to the two groups as part of the analysis of the claims in Group I, and the Examiner is requested to withdraw the restriction requirement. See MPEP § 803, which states that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, ever though it includes claims to distinct or independent inventions." This policy should apply in the present application to avoid unnecessary delay and expense to the Applicants and duplicative examination by the Patent Office.

Applicants hereby provisionally and with traverse elect for continued examination claims of Group 1.

Claim Rejections under 35 U.S.C. §112

The Examiner rejected claims 5, 8, 9 and 22 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reason that the language concerning continuous flow rates in those claims is in the Examiner's view in contradiction with the language of claim 1 concerning variable injection rates. The rejection is traversed. Claims 5, 8, 9, and 22 are canceled without prejudice in this response. Applicants therefore request that the rejection under Section 112 be withdrawn.

Claim Rejections under 35 U.S.C. §103

The Examiner rejected claims 25-26 under 35 U.S.C. §103(a) as being obvious over U.S. 2001/0031978 A1 ("Kipke"), in view of U.S. 5,222,970 ("Reeves"), and further in view of U.S. U.S. 5,894,022 ("Ji"). The Examiner also rejected claims 1, 5-17, 21-22, 27-33, and 35-37 under 35 U.S.C. §103(a) as being obvious over U.S. 5,614,204 ("Cochrum") in view of Kipke. The rejections are respectfully traversed.

It is well known that "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. *Accord* M.P.E.P. § 706.02(j). Moreover, the mere fact that references can be combined or modified does not render the resulting combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F2d 680, 16 U.S.P.Q 2d 1430 (Fed. Cir. 1990).

MPEP Section 2143 sets forth the basic requirements for the Patent and Trademark Office to establish *prima facie* obviousness as follows: "To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

The case law "makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for showing of the teaching or motivation to combine prior art references." *In re Dembiczak,* 175 F.3d 994, 999 (Fed. Cir. 1999); see *also Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665 (Fed.Cir. 2000) This is because "[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight." *Dembiczak,* 175 F.3d at 999. Thus, it is established law that one "cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Ecolochem, Inc. v. Southern Cal. Edison Co.*, 227

F.3d 1361, 1371, 56 USPQ2d 1065 (Fed. Cir. 2000) (citing *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1780, 1783 (Fed. Cir. 1988)).

In this response, independent claims 1, 17, 23, 25, 26, and 27, and their respective dependent claims as well, have been amended to include the limitation "wherein the purified alginate liquid is of molecular weight from about 65,000 to about 200,000." None of the cited references Kipke, Reeves, Ji, and Cochrum teaches or discloses this limitation. For at least this reason, claim 1, 17, 23, 25, 26, and 27, and their respective dependent claims, are not obvious in light of the cited references. The rejections should therefore be withdrawn and the claims allowed as amended.

Applicants acknowledge that in the current Office Action, the Examiner raised this added molecular weight limitation in the context of rejection of Claims 33-34 and 36 under Section 103(a). In this regard, the Office Action acknowledges that Kipke is silent as to the molecular weights of its alginates. However, the Office Action asserts that "...the Kipke application obviously incorporates the same alginates with the same MW because both applications bought from the same source (Pronova) and apparently used the same commercially available alginates..." Based on this assumption, the Office Action concluded that a prima facie case of obviousness had been shown. For at least the reasons stated herein, including without limitation, the Declaration under 37 CFR § 1.132 of inventor Timothy A. Becker, Ph.D. (Exhibit A which is hereby incorporated in full), the rejections are respectfully traversed.

Applicants respectfully assert that the present assumption about nature of the sourced alginates is not supported and therefore the Office Action fails to support a *prima facie* case of obviousness with a shift of burden back to the Applicants. As the Office Action admits, Kipke is completely silent as to molecular weight of any alginate used therein; in fact, the term "molecular weight," or any abbreviation thereof, does not appear anywhere in Kipke. A source of alginate is identified in Kipke as "Pronova" (see e.g., Paragraphs 45, 55, and 56); however, Pronova is disclosed only in conjunction with the purification of alginate (e.g., Par. 65 of Kipke, describing the removal of "impurities"), and not in any way connected with the effect of alginate molecular weight, or differences in molecular weight, on the methods disclosed in Kipke.

By comparison, the present application discloses significant investigation of the effects of molecular weight, and differences in molecular weight, on factors like strength, stability, polymer

yield, and fatigue resistance. See e.g., Example 2, Paragraphs 83-85; Paragraphs. 98-100; and Figures 8a, 8b, and 12. None these factors is disclosed or taught in the context of molecular weight by Kipke. Simply put, there is no disclosure in Kipke of the molecular weight limitation of the present claims, and there is no basis, except in improper hindsight, to attempt to read such as basis on a potent source of alginate material only. For at least these reasons, Kipke fails to disclose the "all the claim limitations" (MPEP 2143), including the molecular weight limitation.

Moreover, as explained in Dr. Becker's Declaration ("Becker Decl."), the assumption that the alginates used in Kipke and the present application are the same is not based in fact. Dr. Becker is the first named inventor on the present application, and he is also a named inventor on Kipke and its related issued patent. Kipke is based in part on Dr. Becker's doctoral work at Arizona State University.

As Dr. Becker explains based on his knowledge of the technology disclosed and discussed in Kipke and the present application, the alginates discussed in both applications were purchased from the same source, Pronova. However, no characterization of molecular weight was available from the vendor on the batches of alginate used at the time of the Kipke application. The only known characterization was the G-acid content and the purity. Therefore, the optimization of alginates by Dr. Becker discussed in the Kipke application originally focused on G acid content and purity only. All testing disclosed in the Kipke application was done with the same batches of alginate. The purified, high G-acid (PHG) batch of alginate was identified as optimal in the Kipke application. (Becker Decl., Paras. 1 – 2, 5 – 6).

Subsequently, when Dr. Becker and co-workers exhausted the original batch of PHG alginate, a new batch of the PHG-class of alginate was ordered from Pronova. The new PHG batch of alginates was made to the specifications disclosed in Kipke as filed. However, Dr. Becker found that the resulting injectable liquid viscosity and final gel strength were significantly different from the original properties disclosed in Kipke. The vendor had sent the same class of alginate (PHG), however, the original batch of PHG alginate was no longer available. In addition, Dr. Becker found that although Pronova had begun classifying the new batches of PHG alginates by their molecular weight, this information was not available for the original batch of PHG alginate. Thus, as Dr.

Becker states, the MW of the alginate material in the Kipke application is unknown. (Becker Decl., Para. 7).

Moreover, as Dr. Becker states, without a way to determine the molecular weight of the original material, part of his original work underlying the present application was to characterize the entire range of PHG alginates then currently available from Pronova. In doing so, Dr. Becker and co-workers discovered the optimal properties of the molecular weight ranges disclosed and claimed in the present application. (Becker Decl., Para. 8).

As shown by the facts in Dr. Becker's Declaration and elsewhere, the assumption in the Office Action that the same alginates with the same molecular weights were used in both Kipke and the present application is not supportable. In fact, for the reasons discussed herein, Kipke (and none of the other cited references) teaches or discloses the molecular weight limitation as claimed, nor can such disclosure be assumed merely because the same vendor was disclosed in each application. Because at least this novel element is lacking in the cited references, the attempted combination of Kipke, Reeves, and Ji fails to support a *prima facie* case of obviousness. For at least these reasons, all rejections under Section 103(a) should be withdrawn, and all rejected claims should be allowed as written or amended.

CONCLUSION

In view of the above, the pending claims are believed to be in condition for allowance. Accordingly, reconsideration and allowance are respectfully requested and the Examiner is respectfully requested to pass this application to issue.

Any fees associated with the filing of this paper have already been identified in the transmittals accompanying this paper. However, if any additional fees are required in connection with the filing of this paper that are not identified in any accompanying transmittals, permission is given to charge Deposit Account 18-0013, under order number 65306-0092 in the name of Rader, Fishman and Grauer PLLC.

If the Examiner has any questions or comments, the Examiner is kindly urged to call the undersigned to facilitate prosecution.

Dated: October 31, 2007

Respectfully submitted,

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